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| 09/660,840   | 09/13/2000  | Paul Remijan         | VSI-005AX           | 7821             |
| 207 7590 12/09/2009<br>WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP<br>TEN POST OFFICE SQUARE<br>BOSTON, MA 02109 |             |                      |                     |                  |
| EXAMINER<br>LEUBECKER, JOHN P  |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/660,840

**Applicant(s)**

REMIJAN ET AL.

**Examiner**

John P. Leubecker

**Art Unit**

3739

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 and 39-80 is/are pending in the application.
- 4a) Of the above claim(s) 19-21, 34, 40-50, 52-58 and 70-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 22-33, 35, 39, 51 and 59-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 9/25/09

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 35 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The independent claims have been amended to be directed to an embodiment in which the light source is incorporated within the handle. The specification fails to disclose that, in the embodiment wherein the light source is incorporated in the handle, the light source is coupled to the illumination waveguide with a *fiber optic element*, as claimed in claims 35 and 59.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-3, 5, 6, 9, 12, 15, 17, 18, 22-31, 33, 35, 39, 51 and 59-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. (U.S. Pat. 5,423,312) in view of Allred, III (U.S. Pat. 4,854,302) and further in view of Kurtzer (U.S. Pat. 5,168,863), Santangelo et al. (U.S. Pat. 4,610,242) and Yarush et al. (U.S. Pat. 5,879,289).

As to claims 1, 28 and 51, Siegmund et al. discloses a probe including an optical waveguide (1) having a light absorbing layer (7), a concentric fiberoptic illumination channel (25, col.4, lines 26-28), a handle (3,27) removably attached (via threads 39, such coupling anticipating first and second coupling elements) to the probe, an optical lens element (5, which can be a positive lens, negative lens or lens system (col.4, lines 9-10), such lens system would encompass a first and second lens; in addition note Figs. 8a-8c and 9) coupled to the distal end of the waveguide, an optical relay (17) mounted in the handle (Fig.1) and optically coupled to a proximal end of the waveguide, and an imaging device (CCD camera) mounted in the handle at a proximal end of the optical relay. The fiberoptic illumination channel comprises an outer sheath (37) and an inner sheath (the metallic, paint or resin layer, col.3, line 62 to col.4, line 8).

Siegmund et al. fails to specify the length and diameter of optical waveguide. However, analogous miniature endoscopes (note Allred, III, Figure 2, col. 4, lines 28-34) are known to include an optical waveguide with a diameter of 2 mm or less and a length of somewhere between 3.3 cm and 11 cm<sup>1</sup>. Since Siegmund et al. fails to teach any particular length and diameter, it would have been obvious to one of ordinary skill in the art to have made the waveguide any desired diameter and length to meet the particular requirements for a certain procedure, and specifically, any length and diameter contemplated in the prior art, since such contemplation suggests a particular need or use for those dimensions in the prior art.

Siegmund et al. further fails to disclose a sterile disposable sheath attached to the probe and extending over the handle. However, Kurtzer teaches an analogous endoscope having such sheath (20). It would have been obvious to one of ordinary skill in the art to have provided a

sheath over the handle of Siegmund et al. to provide a sterile barrier between the handle/camera and the patient to protect the patient from any contamination from elements of the device which are normally handle by the surgeon and to protect the handle/camera from contamination from the patient (e.g., fluids, bacteria).

Siegmund et al. discloses the endoscope as claimed but further fails to disclose a separate cannula that receives the distal end of the probe such that the outer sheath (37) slides within the cannula and that the cannula has a locking mechanism at a proximal end that attaches to the probe. Santangelo et al. demonstrates what is conventional in the endoscope art in that endoscopes are known to be used with a cannula and trocar (stylet) for providing an entry site for the endoscope into the body through the skin (col.1, lines 14-35). Santangelo et al. teaches such cannula/trocar combination (Figs.2,3) wherein the cannula (18,20, Fig.1) includes a locking mechanism (30 in Fig.1 or 31'/36' in Fig.11) at a proximal end to attach to a hub (22) of the endoscope. In addition, Santangelo et al. further teaches a fluid delivery port (51,col.4, lines 62-64) on the cannula for introducing or aspirating fluid through the cannula. It would have been obvious to one of ordinary skill in the endoscope art to have used the endoscope of Siegmund et al. with the cannula/trocar arrangement of Santangelo et al., if not for the fact that such combination of devices are known and used, for the purpose of providing an entry site into the patient (col.1, lines 29-30), protecting the distal end of the endoscope (col.1, lines 41-45) and allowing quick and easily insertion of the endoscope to a proper axial and rotational position (col.1, line 69 to col.2, line 6).

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<sup>1</sup> The probe sleeve (18) is about 3.3 cm in length and the main housing (12) about 7.5 cm in length. Since the optical waveguide (24) extends slightly into the main housing (note proximal end 42, Fig.2), it would have a length of somewhere between 3.3cm and the overall length of about 11 cm.

Siegmund et al. further discloses an external light source (33) that is optically coupled to the illumination channel within the handle and fails to explicitly disclose that the light source is mounted within the handle. Yarush et al. is just one of many references that evidence contemplation in the same art to mount the light source (lamp 94) within the handle of the endoscope (e.g., Yarush et al., 94, Fig.4,5). Yarush et al. teaches that placement of the light source in the handle is one of a number of obvious alternatives including as an alternative to placement of the light source external to the housing (col.5, line 66 to col.6, line 13). Since both Siegmund et al. and Yarush et al. teach arrangements for providing light to an endoscope illumination channel, and Yarush et al. teach that either an external light source or one mounted in the handle could be used, it would have been obvious to one of ordinary skill in the art to substitute one arrangement for the other to achieve the predictable result of providing light to the illumination channel of the endoscope. The skilled artisan would further recognize that mounting the light source within the handle eliminates the encumbrance of a separate light source and optical cable, which makes the device more portable, and reduces attenuation of light between the light source and illumination channel (by reducing the distance that light needs to travel between the light source and distal end of the endoscope), thus allowing for a less intense and power consuming source.

Clearly a diameter of less than 2 mm, as taught by Allred, III would encompass the diameters of claims 2 and 3. As to claim 5, 6, 30 and 31, the waveguide of Siegmund et al. comprises a high-index glass rod of a refractive index greater than 1 (which includes 1.6). As to claim 9, note col.4, lines 3-8. As to claim 12, the outer sheath (37) comprises a metal (col.4, lines 23-25). As to claims 18 and 68, the cannula tip (21) forms a needle (note tapered pointed

end 21, Fig.1of Santangelo). As to claims 17, 22 and 39, an image from a CCD camera is inherently viewed on a display. As to claims 23, 24, 27, 35, 59, 61 and 62, note that upon modification to include a light source within the handle, as taught by Yarush et al., optical fibers (25) would be optically coupled to the light source via a lens (focused end lens, Yarush et al, col.6, lines 14-18) and fiber optic connector (input port of fiber bundle 112, Yarush et al., col.6, lines 20-28). As to claims 26, 63 and 64, note in Kurtzer that the sterile barrier (20) is attached to the probe via a disposable probe element (13, Fig.6, col.5, lines 37-59). As to claim 60, note ring of optical fibers (25). As to claim 67, note col.6, lines 17-26 regarding a locking mechanism (70) and further note the locking mechanism of Santangelo et al. As to claim 69, the trocar (60, Fig.3) constitutes a stylet.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III, Kurtzer, Santangelo et al. and Yarush et al., as described above, and further in view of Woodard et al. (U.S. Pat. 5,947,958).

Although the different distal tip configurations (71,72, Figs. 8b,8c) of Siegmund et al. provide dispersive properties and could be considered as a “ring”, Woodard et al. explicitly teach that, in an alternative to forming the tip, that other dispersive elements including lenses and refractive gradients could be used (col.5, lines 39-44). Thus, it would be obvious to one of ordinary skill in the art to have used a separate dispersive element in the device of Siegmund et al. as an obvious design alternative for dispersing the illumination light.

6. Claims 7, 10, 13, 14, 16 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III, Kurtzer, Santangelo et al and Yarush et al.

As to claims 7 and 10, Siegmund et al. fails to specify the thickness of the light absorbing layer and the wall thickness of the illumination channel. However, inasmuch as neither Applicant nor the prior art of record attribute any significance to the precise thickness of these layers (Applicant discloses the claimed ranges simply as preferred), the choice of such thicknesses would have been obvious to the artisan if routine experimentation proved such to be suitable. Where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Since miniaturization is a key design consideration in the non-invasiveness of endoscopic devices and thicknesses in the claimed ranges are not extraordinary in the art, such claimed ranges would be considered obvious and desirable.

As to claim 13, Siegmund et al. explicitly teaches that the outer sheath can be made from metals or plastics (col.5, lines 2-3) but fails to specify polyamide. If not inherently encompassed by "plastics", Siegmund's teaching would prompt one of ordinary skill in the art to draw from common knowledge. Polyamide is a well known plastic material. It would therefore be obvious to one of ordinary skill in the art to have used polyamide. Evidence that polyamide is a well known plastic material will be provided only if Applicant disagrees on record to such notice.

As to claim 14, Siegmund et al. fails to mention the thickness of the outer sheath. However, inasmuch as neither Applicant nor the prior art of record attribute any significance to the precise thickness of the sheath (Applicant discloses the claimed ranges simply as preferred),



the choice of such thickness would have been obvious to the artisan if routine experimentation proved such to be suitable. Where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Since miniaturization is a key design consideration in the non-invasiveness of endoscopic devices and the claimed is not extraordinary in the art, such claimed thickness would be considered obvious.

As to claim 16, Siegmund et al. fails to disclose the material of the lens. Both glass and plastic lenses are notoriously well known in the art. Either can be used for the same purposes and both have advantages and disadvantages. It would have been obvious to one of ordinary skill in the art to have used plastic for the material of the lens of Siegmund et al. as a matter of design choice.

As to claim 32, Siegmund et al. fails to disclose the specific properties of the high index of refraction glass rod (i.e., that it is an F2 or F7 glass). If not inherently encompassed by "high index of refraction glass", Siegmund's teaching would prompt one of ordinary skill in the art to draw from common knowledge. F2 and F7 glasses are well known types of glass. It would have therefore been obvious to one of ordinary skill in the art to have used well known types of glass such as F2 and F7 glass. Evidence that these are well known types of glass will be provided only if Applicant disagrees on record to such notice.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III, Kurtzer, Santangelo et al., and Yarush et al., as described above, and further in view of Eastman (U.S. Pat. 5,319,731).

Siegmund et al. disclose the device as described above wherein the light absorbing layer is a hydrogen-fired blackened surface and thus fails to disclose such layer as being comprised of extramural absorption glass. Since such extramural absorption glass is known to provide similar properties (e.g., attenuate stray light) (note Eastman, col.1, lines 46-65 and col.5, lines 35-53), it would have been obvious to the skilled artisan to have used extramural absorption glass for the absorption layer as an obvious design alternative. Use of such absorption glass would simplify the application of the absorbing layer by eliminating the hydrogen-firing process while still providing good image quality.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Allred III, Kurtzer, Santangelo et al., and Yarush et al., as described above, and further in view of Strack (U.S. Pat. 3,902,880).

Since Siegmund et al., as described above, does not mention any specific optical properties for the illumination channel, one of ordinary skill in the art would draw from conventional knowledge in the art when reducing such device to practice. Strack evidences that illumination core materials can have a refractive index of 1.5 to 1.81 (col.3, lines 12-17) with the refractive index of the cladding being lower. The claimed ranges are inherent properties of typically known materials (e.g., glasses, plastics) that have been used for the same purposes (e.g.,

illumination). Clearly, such specific optical properties would be obvious to one of ordinary skill in the art as they are inherent in the materials that would conventionally be used.

### ***Response to Arguments***

9. Applicant's arguments filed August 26, 2009 have been fully considered but they are not persuasive.

Applicants traverse the previous rejections alleging that if Siegmund were constructed at the claimed size, it would result in a loss in image size and resolution, and thereby compromise diagnostic value. So the question is: since Siegmund discloses a substantially similar optical arrangement (which respect to optical properties), then how is Applicant's optical arrangement any better? Perhaps the answer to this question will provide the feature which can distinguish Applicant's invention from the prior art.

Regarding the newly added limitation directed to the light source being mounted within the handle, this feature has been contemplated in the art and is addressed above.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lafferty et al. (U.S. Pat. 5,329,936)

Lafferty et al. (U.S. Pat. 5,323,767)

Steinberg (U.S. Pat. 5,630,783)

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Leubecker/  
Primary Examiner  
Art Unit 3739

jpl